

§ 158.350

40 CFR Ch. I (7–1–11 Edition)

be isolated, a statement of the composition of the practical equivalent of the technical grade of the active ingredient must be submitted.

§ 158.350 Certified limits.

The applicant must propose certified limits for the ingredients in the product. Certified limits become legally binding limits upon approval of the application. Certified limits will apply to the product from the date of production to date of use. If the product label bears a statement prohibiting use after a certain date, the certified limits will apply only until that date.

(a) *Ingredients for which certified limits are required.* Certified limits are required on the following ingredients of a pesticide product:

- (1) An upper and lower limit for each active ingredient.
- (2) An upper and lower limit for each inert ingredient.

(3) If the product is a technical grade of active ingredient or is produced by an integrated system, an upper limit for each impurity of toxicological significance associated with the active ingredient and found to be present in any sample of the product.

(4) On a case-by-case basis, certified limits for other ingredients or impurities as specified by EPA.

(b) *EPA determination of standard certified limits for active and inert ingredients.* (1) Unless the applicant proposes different limits as provided in paragraph (c) of this section, the upper and lower certified limits for active and inert ingredients will be determined by EPA. EPA will calculate the certified limits on the basis of the nominal concentration of the ingredient in the product, according to the table in paragraph (b)(2) of this section.

(2) Table of standard certified limits.

STANDARD CERTIFIED LIMITS

If the nominal concentration (N) for the ingredient and percentage by weight for the ingredient is:	The certified limits for that ingredient will be as follows:	
	Upper Limit	Lower Limit
N≤1.0%	N + 10%N	N - 10%N
1.0% ≤N ≤20.0%	N + 5%N	N - 5%N
20.0% ≤N ≤100.0%	N + 3%N	N - 3%N

(c) *Applicant proposed limits.* (1) The applicant may propose a certified limit for an active or inert ingredient that differs from the standard certified limit calculated according to paragraph (b)(2) of this section.

(2) If certified limits are required for impurities, the applicants must propose a certified limit. The standard certified limits may not be used for such substances.

(3) Certified limits should:

- (i) Be based on a consideration of the variability of the concentration of the ingredient in the product when good manufacturing practices and normal quality control procedures are used.
- (ii) Allow for all sources of variability likely to be encountered in the production process.
- (iii) Take into account the stability of the ingredient in the product and the possible formation of impurities

between production and sale or distribution.

(4) The applicant may include an explanation of the basis of his proposed certified limits, including how the certified limits were arrived at (e.g., sample analysis, quantitative estimate based on production process), and its accuracy and precision. This will be particularly useful if the range of the certified limit for an active or inert ingredient is greater than the standard certified limits.

(d) *Special cases.* If the Agency finds unacceptable any certified limit (either standard, or applicant proposed), the Agency will inform the registrant or applicant of its determination and will provide supporting reasons. The Agency may also recommend alternative limits to the applicant. The Agency may require, on a case-by-case basis, any or all of the following:

- (1) More precise limits.

(2) More thorough explanation of how the certified limits were determined.

(3) A narrower range between the upper and lower certified limits than that proposed.

(e) *Certification statement.* The applicant must certify the accuracy of the information presented, and that the certified limits of the ingredients will be maintained. The following statement, signed by the authorized representative of the company, is acceptable:

I hereby certify that, for purposes of FIFRA sec. 12(a)(1)(C), the description of the composition of [*insert product name*], EPA Reg. No. [*insert registration number*], refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that: (1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified for that ingredient in a currently approved Statement of Formula (or as calculated by the Agency); and (2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

§ 158.355 Enforcement analytical method.

An analytical method suitable for enforcement purposes must be provided for each active ingredient in the product and for each other ingredient or impurity that the Agency determines to be toxicologically significant.

Subpart E—Product Performance

§ 158.400 Product performance data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product performance data requirements for a particular pesticide product. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. Data are also required for the general use patterns of forestry use, residential outdoor use, and indoor use, which includes both food and nonfood uses.

(c) *Key.* CR=Conditionally required; NR=Not required; R=Required; EP=End-use product; MP=Manufacturing-use product; TEP=Typical end-use product.

(d) *Table.* The following table lists the data requirements that pertain to product performance. The table notes are shown in paragraph (e) of this section.